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RECORD OF ORAL HEARING

U.S. PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte RUDI BRANDS

Appeal No. 2010-000543
Application No. 09/582,342
Technology Center 1600

Oral Hearing Held: January 19, 2011

Before LORA GREEN, FRANCISCO C. PRATS and STEPHEN WALSH, *Administrative Patent Judges.*

APPEARANCES:

ON BEHALF OF THE APPELLANT:

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The above-entitled matter came on for hearing on Wednesday, January 19, 2011 commencing at 9:40 a.m., at the U.S. Patent and Trademark Office, 600 Dulany Street, Alexandria, Virginia, before Dawn A. Brown, Notary Public.

PROCEEDINGS

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THE USHER: Calendar Number 46, Appeal Number 2010-000543.

Ms. Gupta.

JUDGE GREEN: If you have a card or you can spell your name into the record for the court reporter. We are familiar with the record and you have 20 minutes whenever you would like to begin.

MS. GUPTA: Would you also like me to state my name for the record?

JUDGE GREEN: Yes, please.

MS. GUPTA: My name is Jennifer Gupta. I'm here with Finnegan, Henderson. And today we'll be discussing Application Number 09/582,342. This application has quite a long prosecution history, but I think it is whittled down to one 103 rejection and that is over three references -- Griffiths, which is a handbook, and two Internet articles, one entitled "Friendship Cake/Bread History" and the other entitled "Amish Friendship Bread."

The Supreme Court in KSR recognized there is a number of rationales to support a conclusion of obviousness. However, none of those rationales support the Examiner's conclusion of obviousness in the present application. The Examiner primarily relies upon the teaching-suggestion-motivation rationale. And under this rationale, the Examiner must identify the teaching, suggestion or motivation to modify or combine the references as well as a reasonable expectation of success to meet the proposed modification. We don't believe the Examiner has met that burden here.

The primary reference, Griffiths, discloses protocols for scaling off the suspension in anchorage-dependent cells. Anchorage-dependent cells are not

homogeneously dividing. They are attached to microcarriers.
However, the secondary references, they're disclosing process of preparing bread. And unlike the anchorage-dependent cells, they use yeast cells, and the yeast cells used in preparing bread are homogeneously divided in dough.
You know, while modifications and variations to improve methods can be imported across different fields of art, in the present case, there is no reason that one of ordinary skill in the art would import the techniques used in making bread even if cell cultures are employed for use in a method where the production of a biological and especially given that the cell cultures used in bread are different than the anchorage-dependent cells.
As I said, the yeast cells are homogeneously divided in dough and the anchorage-dependent cells are not. And the art here teaches how to handle the anchorage-dependent cells. Griffiths teaches protocols for scaling up in anchorage-dependent cells and recognizes the difficulties in doing so.
Because of the difficulties which are homogeneity problems associated with scaling up anchorage-dependent cells, Griffiths teaches that suspension cultures, not anchorage-dependent cultures, are always the preferred culture method.
And another prior art reference, Groner, also recognizes the difficulties associated with the scaling of the anchorage-dependent scales. It talks about the scaling-up method necessitates opening the individual cell culture vessel several times and is very labor-intensive, and it also creates a danger of increased contamination of the cell culture.
To address those problems, Groner converts the anchorage-dependent cell to cells that are grown in suspension to enable a better scaling-up process. So

based on those teachings, one of ordinary skill in the art would be unlikely to use a splitting process, such as the repeated discontinuous process that we're claiming, when using anchorage-dependent cells for the production of biological.

And since the art teaches how to handle the anchorage-dependent cells, it seems unlikely that one of ordinary skill in the art would then look to yeast cells rather than what the art teaches for the production of a biological.

JUDGE GREEN: But then how do you have cells that you're going to use for scale-up for the next batch? I mean, don't you have to start -- are you going to reengineer your cells every time?

MS. GUPTA: No. The process is they scale that particular volume. They divide it. They take a first part, a majority of the cells for producing the biological. They leave a small amount remaining, 10 to 20 percent approximately, and that they use to reseed to create a new preproduction batch. And so they are always regenerating cells with the remaining cells leftover. So it creates a cell bank to continue to use.

JUDGE WALSH: As I understand the Examiner's view, the Examiner interpreted Griffiths as showing how to grow up or scale up all the cells. And there was a particular section of Griffiths that you and the Examiner seem to disagree on significantly.

The Examiner pointed to the passage where Griffiths says at the point at which you're basically ready to harvest the cells, it says the cells will detach and can be harvested, diluted in fresh medium and serum and passaged on.

Now, the Examiner says the word passaged on would include the concept of using some of those cells for production of a biological and using some of the

cells as the basis for your new expansion or new scale-up. And I understood the Examiner to be saying this is a well-known concept and it is even used in things like making bread where you don't throw out or use up all of your bread because you then have nothing to work with as Judge Green's question was. But then if Griffiths was actually instructing people use up all the cells you have, then what? Do you have to start over and reengineer?

I think as I understand that question, that was what the Examiner is getting at, more practical to take some of these cells and scale them up again. I understood that to be the Examiner's view. And what is wrong with that?

MS. GUPTA: I think the Examiner is saying that splitting the cell culture is sort of inherent in the passaging on in Griffiths. But it is my understanding that passaging of cells as it is described in Griffiths involves transferring all the existing cells from one vessel to another. It is not splitting.

JUDGE WALSH: Do you have any evidence? A single vessel to a single other vessel?

MS. GUPTA: Correct. As you -- in sequence, you continue to do that and to get larger cells. You know, one of ordinary skill in the art may interpret that some cells are left behind in a previous vessel, but it is my understanding that those cells that are left behind are not used as a seed for subsequent preproduction batch. They're just discarded. They're not used.

JUDGE WALSH: First question: Do you have any evidence that your impression is shared by people of skill in the art?

MS. GUPTA: I have spoken with the inventor.

JUDGE WALSH: Evidence in the record that we can review.

MS. GUPTA: Just based on what Griffiths teaches and what the other

references -- Griffiths and Groner teach about the scaling up of anchorage-dependent cells.

JUDGE WALSH: Second question: Even if that is correct, why would it not have been obvious to do what the Examiner said, split these and save some of them to scale up again for your next batch?

MS. GUPTA: I think that goes to what Groner is talking about.

JUDGE WALSH: Where is Groner in the record?

MS. GUPTA: It is WO 97/37000. It is discussed in the --

JUDGE WALSH: Did you provide that in your Evidence Appendix?

MS. GUPTA: Yeah. We discuss it in the Appeal Brief and the Reply Brief.

JUDGE WALSH: Actually, the Evidence Appendix seems to indicate no evidence.

MS. GUPTA: We don't have any declaration evidence. It is prior art that is of record, and it recognizes the difficulties in the scaling up of anchorage-dependent cells. So it is not merely a combination of these known techniques, the only predictable results. You know, the results of combining these techniques are not predictable.

And the art at the time recognizes the difficulties in the scaling up of anchorage-dependent cells being, you know, labor intensive as well as the danger of contamination of the cells. Because as you continue to culture them and you have to open up the vessels multiple times, it increases the microorganisms in the culture vessels.

And so the Applicants have discovered a way to do the splitting process where they're using the remaining cells and scaling up, and that -- it ensures the safety of the cell line and it guarantees less contamination because they're

using the cells that they have already cultured up and the remaining cells to use as a seed for a later preproduction batch.

JUDGE GREEN: Is your argument that because in the prior art they have already scaled up and they leave 20 percent behind to start their next batch that you don't have to go through the scaling up again and that is why the art teaches away from the claimed invention?

MS. GUPTA: I think the art teaches away from the claimed invention because the prior art teaches -- based on the difficulties with scaling up the anchorage-dependent cells, it teaches using suspension cells rather than the anchorage-dependent cells which we're using.

And so you wouldn't use the anchorage -- you would take anchorage-dependent cells and convert them to suspension cells, and that is what Groner teaches rather than take the anchorage-dependent cells and split them and use a later -- the remaining cells leftover for the seed.

JUDGE GREEN: Okay.

MS. GUPTA: And I think also the fact that the art already tells how to handle the anchorage-dependent cells that you wouldn't look outside to these methods of culturing yeast cells for bread when trying to devise a process of using anchorage-dependent cells for preparing the biological.

JUDGE GREEN: I think we understand your case. Thank you very much.

(Whereupon, the proceedings at 9:51 a.m. were concluded.)